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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,222	06/29/2000	Kirk R. Thomas	2323-139-II	7631

6449 7590 07/10/2002

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EXAMINER

TON, THAIAN N

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 07/10/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application N .

09/606,222

Applicant(s)

THOMAS ET AL.

Examiner

Thaian N. Ton

Art Unit

1632

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.**

Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

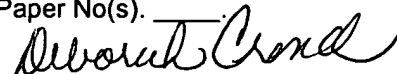
Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 1-17, 19-34 and 37.

Claim(s) withdrawn from consideration: 18, 36.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

  
**DEBORAH CROUCH**  
PRIMARY EXAMINER  
GROUP 1807/630

Continuation of 2. NOTE: The terms, "regulatable manner" and "regulatable promoter" require new search and consideration.

Continuation of 5. does NOT place the application in condition for allowance because: The claimed invention is directed to methods for deleting a nucleic acid sequence in specified tissues of an organism, whereby the sequence comprises a recombinase site, a tissue-specific promoter, a recombinase gene, a foreign DNA and a recombinase site, further growing the organism such that the tissue-specific promoter is active, the recombinase gene is expressed in the specified tissue and the foreign DNA is deleted. Applicants argue that the claimed method does not require the introduction of the DNA constructs into embryonic stem (ES) cells for the invention to work, further, Applicants state they are not creating transgenic animals and argue that the Examiner has not provided any sound reasons as to why the presently claimed invention would not be enabled by the skilled artisan. Applicants further argue that the Examiner has not specified an independent basis for rejection claim 20, and the claims that depend therefrom for lack of [see p. 5 of Applicants' Response, filed 6/12/02, Paper No. 11]. In response, the Examiner reiterates that the claimed invention reads on the deletion of nucleic acid sequences from a DNA molecule that has been introduced into an organism, and the expression of a recombinase gene in specific tissues of the organisms which leads to the deletion of foreign DNA [see, for example, claim 1]. As such, although the claims are not directed to the generation of transgenic animals, the claims methods require the use of transgenic animal which has been introduced with the claimed nucleic acid construct. As such, the Examiner reiterates that the claimed invention is dependent upon the state of the art of transgenesis, and further dependent upon the present availability of ES cells for the production of such transgenic animals [see p. 5 of the prior Office action]. As such, the Examiner maintains that ES cells are elements that would be considered essential for the invention to work. Further, with regard to the rejection of claim 20, under 112, 1<sup>st</sup> paragraph, the rejection of this claim is based upon its intended use [to delete sequences in a tissue-specific manner in specified tissues of a transgenic animal]. Neither the specification nor Applicants have provided any other use for the claimed construct other than the described method, which is not enabling, as stated supra, and as such, the claimed construct is not enabled.